

CRAVATH, SWAINE & MOORE LLP

JOHN W. WHITE
 EVAN R. CHESLER
 RICHARD LEVIN
 KRIS F. HEINZELMAN
 B. ROBBINS KISSLING
 ROGER D. TURNER
 PHILIP A. GELSTON
 RORY O. MILLSON
 RICHARD W. CLARY
 WILLIAM P. ROGERS, JR.
 JAMES D. COOPER
 STEPHEN L. GORDON
 DANIEL L. MOSLEY
 ROBERT H. BARON
 KEVIN J. GREHAN
 C. ALLEN PARKER
 SUSAN WEBSTER
 DAVID MERCADO
 ROWAN D. WILSON
 CHRISTINE A. VARNEY
 PETER T. BARBUR
 SANDRA C. GOLDSTEIN
 THOMAS G. RAFFERTY
 MICHAEL S. GOLDMAN
 RICHARD HALL

JULIE A. NORTH
 ANDREW W. NEEDHAM
 STEPHEN L. BURNS
 KEITH R. HUMMEL
 DAVID J. KAPPUS
 DANIEL SLIFKIN
 ROBERT I. TOWNSEND, III
 WILLIAM J. WHELAN, III
 SCOTT A. BARSAY
 PHILIP J. BOECKMAN
 ROGER G. BROOKS
 WILLIAM V. FOGG
 FAIZA J. SAEED
 RICHARD J. STARK
 THOMAS E. DUNN
 MARK I. GREENE
 DAVID R. MARRIOTT
 MICHAEL A. PASKIN
 ANDREW J. PITTS
 MICHAEL T. REYNOLDS
 ANTONY L. RYAN
 GEORGE E. ZOBITZ
 GEORGE A. STEPHANAKIS
 DARIN P. MCATEE
 GARY A. BORNSTEIN

WORLDWIDE PLAZA
 825 EIGHTH AVENUE
 NEW YORK, NY 10019-7475

TELEPHONE: +1-212-474-1000
 FACSIMILE: +1-212-474-3700

CITYPOINT
 ONE ROPE MAKER STREET
 LONDON EC2Y 9HR
 TELEPHONE: +44-20-7453-1000
 FACSIMILE: +44-20-7860-1150

WRITER'S DIRECT DIAL NUMBER

(212) 474-1243

TIMOTHY G. CAMERON
 KARIN A. DEMASI
 LIZABETHANN R. EISEN
 DAVID S. FINKELSTEIN
 DAVID GREENWALD
 RACHEL G. SKAISTIS
 PAUL H. ZUMBRO
 JOEL F. HEROLD
 ERIC W. HILFERS
 GEORGE F. SCHOEN
 ERIK R. TAVZEL
 CRAIG F. ARCELLA
 TEENA-ANN V. SANKOORIKAL
 ANDREW R. THOMPSON
 DAMIEN R. ZOUBEK
 LAUREN ANGELILLI
 TATIANA LAPUSHCHIK
 ERIC L. SCHIELE
 ALYSSA K. CAPLES
 JENNIFER S. CONWAY
 MINH VAN NGO
 KEVIN J. ORSINI
 MATTHEW MORREALE
 JOHN D. BURETTA
 J. WESLEY EARNHARDT

YONATAN EVEN
 BENJAMIN GRUENSTEIN
 JOSEPH D. ZAVAGLIA
 STEPHEN M. KESSING
 LAUREN A. MOSKOWITZ
 DAVID J. PERKINS
 JOHNNY G. SKUMPIJA
 J. LEONARD TETI, II
 D. SCOTT BENNETT
 TING S. CHEN
 CHRISTOPHER K. FARGO
 KENNETH C. HALCOM
 DAVID M. STUART
 JONATHAN L. DAVIS
 AARON M. GRUBER
 O. KEITH HALLAM, III
 OMID H. NASAB

SPECIAL COUNSEL
 SAMUEL C. BUTLER
 GEORGE J. GILLESPIE, III

OF COUNSEL
 MICHAEL L. SCHLER

May 13, 2015

U.S. ex rel. Kester, et al. v. Novartis Pharmaceuticals Corp., et al.,
No. 11 Civ. 8196 (CM) (JCF)

Dear Judge Francis:

We represent Defendant Novartis Pharmaceuticals Corporation (“Novartis”) in the above-referenced matter. We write in response to the letter that Relator David M. Kester submitted to the Court on May 5, 2015 (“Relator’s Ltr.”) (ECF No. 423).

Relator requests that the Court order Novartis to (1) apply broader search terms in reviewing and producing documents subject to its waiver of the attorney-client privilege concerning the challenged Exjade activities; (2) produce documents concerning legal advice given after the events at issue in this case, even though those documents do not bear on Novartis’s intent during the relevant time frame; (3) produce privileged documents concerning an unrelated litigation brought against a different company and privileged documents concerning a drug not at issue in this case; and (4) produce documents from two additional custodians, even though Relator has had information and documents concerning these individuals for months. Relator also requests that the Court order Novartis to create a financial analysis of Novartis’s revenue and margins on sales of Exjade through the EPASS pharmacies, even though Novartis already has produced the available underlying sales information from its files and does not maintain revenue and margin information by pharmacy as has been requested. For the reasons set forth below, we respectfully request that the Court deny the relief sought.

I. Relator’s Requests Concerning Exjade Legal Advice Should Be Denied.

During the March 27, 2015 conference, Judge McMahon stated that any extension of the schedule was not to be interpreted as a license for the Government or Relator to seek significant additional discovery from Novartis. Judge McMahon noted that the Government and Relator “started this by complaining to me you had a million documents . . . dumped on you, and now you want more”. (Mar. 27, 2015 Conf. Tr. 9:7-9 (ECF No. 410).) Judge McMahon also stated that, in light of the approximately 60 million pages of documents Novartis had already produced in this litigation and in the Government’s previous civil investigation, she did not “anticipate that there will be a great deal of additional discovery from Novartis”. (Id. Tr. 22:16-

18.) Judge McMahon then adjourned the June 26, 2015 trial-ready date and set June 26 as the deadline for submission of the pre-trial order. (Apr. 6, 2015 Order (ECF No. 406).)

A. Relator's Request to Apply Broader Search Terms to the Files of Novartis's Lawyer Custodians Is Unwarranted.

In collecting and producing potentially responsive documents, a party must "conduct a diligent search, which involves developing a reasonably comprehensive search strategy". Treppel v. Biovail Corp., 233 F.R.D. 363, 374 (S.D.N.Y. 2006). "The standard for the production of ESI is not perfection." Chen-Oster v. Goldman, Sachs & Co., 285 F.R.D. 294, 306 (S.D.N.Y. 2012). Rather, a party must use "reasonable selection criteria", including search terms. Treppel, 233 F.R.D. at 374 (quoting The Sedona Principles; Best Practices Recommendations & Principles for Addressing Electronic Document Production, Principle 11 (2003)).

Relator complains that "Novartis unilaterally chose the search terms it used to identify additional documents" and "first provided [those search terms] to plaintiffs on April 21, 2015". (Relator's Ltr. at 5.) Novartis used search terms it believes were appropriate (as set forth below). And although Novartis first informed the parties in February that it was collecting and reviewing relevant documents concerning Exjade legal advice (Novartis Ex. A at 8), Relator did not ask Novartis to provide its search terms until April 15. (Relator's Ex. 3 (April 15, 2015 10:57 p.m. email).) Novartis disclosed its search terms to Relator within days of Relator's request for them.

Relator's concerns about the completeness of Novartis's search of its lawyers' files are unfounded. Novartis first screened for documents that contained the term Exjade, variations of the term "specialty pharmacy" or references to one of the specialty pharmacies at issue in this case (BioScrip, Accredo or US Bioservices). Novartis then searched within these documents for any of 37 terms designed to identify documents concerning the activities challenged by Relator and the Government (such as "adher*", "discount*", "rebate*", "allocat*" or "rotat*"), documents concerning the relevant law (such as "FCA", "false claims", "fraud and abuse" or "AKS"), documents concerning entities at issue in this case ("BioScrip", "Accredo", "US Bioservices", "EPASS" or "LASH") and documents concerning or communications with Novartis's relevant outside counsel (variations of Joe Metro).

After reviewing the search terms Novartis used, Relator's counsel insisted that Novartis apply 315 new combinations of search terms for seven of its lawyer custodians. (See Novartis Ex. B at 1.) Those combinations would require Novartis to review more than 200,000 documents, in addition to those it already has reviewed and the approximately 19,000 waiver documents it already has produced. Novartis's counsel attempted to negotiate a more limited date range and set of search terms,¹ but the parties were unable to agree.

¹ Relator incorrectly states that "plaintiffs agreed to narrow the date range of the additional searches". (Relator's Ltr. at 5.) In fact, Relator's counsel tentatively agreed to narrow the date range of additional searches Relator had proposed for Novartis's non-lawyer custodians but

Relator now asks that the Court order Novartis to apply a subset of the terms Relator originally had proposed to Novartis. (Relator's Ltr. at 6-7.) Although Relator's newly-proposed search terms would require the review of fewer documents than the original proposal, the terms are still overbroad (and, we submit, unwarranted). Among other things, Relator's proposal to add five new search terms to the First Group and five new search terms to the Second Group would require Novartis to search using 260 new combinations of terms, resulting in the review of approximately 150,000 documents. And the terms themselves—for example, the combination of “Exjade” and “risk” without any other restrictions—would capture documents concerning issues far afield from the activities challenged in this litigation. (For example, documents concerning Novartis financial disclosures and human resources materials.) Because the search terms Novartis initially applied were “reasonably comprehensive”, Treppel, 233 F.R.D. at 374, there is simply no basis to require Novartis to apply the additional terms proposed by Relator, particularly considering Relator's delay in making his request.

Relator also complains about the use of a “separate search protocol for searching documents in the custody of outside counsel Joseph Metro” at the law firm of Reed Smith LLP. (Relator's Ltr. at 7.) The search protocol for Mr. Metro's documents was separate because Mr. Metro's documents are stored differently from Novartis's documents. The vast majority of Reed Smith's documents concerning Mr. Metro's work for Novartis are stored in paper form. Contrary to Relator's suggestion, Novartis did not apply search terms to those documents at all. Rather, Mr. Metro personally reviewed those hard copy documents and provided any that were relevant to the Exjade-related activities that plaintiffs have challenged in this litigation. Other paper documents were not produced because they were not relevant to this case; neither Novartis nor Reed Smith has an obligation to create a privilege log of such nonresponsive documents.

Novartis applied search terms only to Reed Smith's electronic documents. Although Novartis believes those terms were reasonable, given the small number of electronic documents in Reed Smith's files and to resolve this issue expediently, Novartis has reviewed electronic documents in Reed Smith's files that hit on Relator's suggested standalone search terms of “Exjade” or “EPASS” (Relator's Ltr. at 8). All but two of the relevant documents that resulted from this search are exact duplicates of documents already produced to Relator. Novartis will produce the two remaining documents, the content of which already was included within previously produced documents.

B. Novartis Has Already Searched for “Later-In-Time Communications” That Bear on its Intent with Respect to the Challenged Activities.

Relator seeks “later-in-time communications” between Novartis and its counsel, regardless of whether those communications have any relevance to the advice given during the period of alleged wrongdoing. (Relator's Ltr. 8-9.) Relator's request should be denied.

Relator contends that “the scope of the waiver is not based on a rigid timeline”. (Relator's Ltr. at 8.) Novartis agrees. Despite Relator's claims to the contrary, Novartis has not taken the position that “later-in-time legal advice cannot be relevant to [] scienter”. (Relator's

declined to narrow the proposed date range with respect to the lawyer custodians. Notably, Relator's letter still does not specify a proposed date range with respect to the lawyer custodians.

Ltr. at 9.) Instead, consistent with its representation to the Court, Novartis undertook a search for all responsive communications from the beginning of the relevant time period through 2013 that bear on Novartis's state of mind with respect to the Exjade activities challenged in the complaint. (Mar. 4, 2015 Conf. Tr. 16:17-25 (ECF No. 369).) Because the challenged activities ended in May 2012, the vast majority of post-2012 documents discussing Exjade do not bear on Novartis's intent with respect to those activities. Post-2012 documents are relevant if they retrospectively discuss what Novartis was advised or believed in connection with the activities during the time period at issue in the Complaint. Novartis has searched for all such documents for an additional year and a half after the challenged activities ceased, through the end of 2013.

Relator bases his argument upon a single document: a 2013 memorandum from Mr. Metro, outside counsel, to Steve Goldfarb, Vice President of Legal for Novartis Pharmaceuticals Corporation. (Relator's Ltr. at 8; Relator's Ex. 5.) Relator has requested a spreadsheet referred to in that document as well as any drafts or other documents relating to it. However, the context of the memorandum and associated spreadsheet demonstrates why the memorandum was produced in error and why both the memorandum and spreadsheet are outside the scope of Novartis's privilege waiver.

Mr. Metro created this memorandum
REDACTED

And at the time Novartis waived the privilege concerning certain Exjade-related activities, it explicitly did not waive privilege with respect to the defense of this litigation or preparation for future litigation. (See Novartis Ex. A at 4.) Novartis has requested the return or destruction of this document pursuant to the Rule 502(d) Order entered in this case (March 4, 2015 Order (ECF No. 363)).

Finally, Relator contends that Novartis should not be permitted to "limit the temporal scope of its waiver" because doing so would be "particularly unfair". (Relator's Ltr. at 9.) However, the cases cited by Relator do not support that argument. For example, in Arista Records LLC v. Lime Grp. LLC, a defendant asserted a good faith defense without disclosing any privileged communications. No. 06 CV 5936, 2011 WL 1642434, at *2 (S.D.N.Y. Apr. 20, 2011). And in Bank Brussels Lambert v. Credit Lyonnais (Suisse) S.A., a party had declined to produce relevant documents created after a challenged financing, even though the post-financing documents shed light on the party's pre-financing state of mind, and even though the party itself had sought to rely on documents created after the financing. No. 93 CIV. 6876, 1995 WL

² "Goldfarb Decl. __" refers to the Declaration of Steven Goldfarb submitted with this letter.

598971, at *5-6 (S.D.N.Y. Oct. 11, 1995). In contrast, Novartis has not made a selective disclosure of documents, but has searched for and produced any documents bearing on its intent with respect to the Exjade challenged activities, whether the documents were created before or after those activities occurred.³

C. There Is No Basis for Novartis To Disclose Legal Advice Unrelated to Exjade and Outside the Scope of Its Waiver.

Relator claims that Novartis should unredact two documents because they relate to “highly similar incentive schemes” as Exjade. (Relator’s Ltr. at 9-10.) Novartis is providing Your Honor with unredacted copies of the two documents for in camera review. (Novartis Exs. C and D.)

The first document is an email recounting a conversation between an internal and outside lawyer for Novartis concerning the “Omnicare/J&J matter”. (Relator’s Ex. 6.) The unredacted portion of the document notes that part of the discussion concerned

REDACTED

(Id.) Novartis’s outside counsel concluded that the
REDACTED

(Id.) Thus the unredacted portions of the email disclose the substance of the advice conveyed on this matter to the extent it relates to Exjade.

The redacted portion of the email, on the other hand, concerns a separate part of the conversation relaying how Novartis’s outside lawyer interpreted the Omnicare/J&J matter with respect to issues unrelated to the Exjade allegations. Therefore the redacted text is not within the scope of Novartis’s waiver.

The second document is a set of handwritten notes with a one-line redaction of a statement concerning Novartis’s TOBI drug. (Relator’s Ex. 7.) The undated notes were produced because Novartis’s review attorneys believed that the unredacted portions of the document concerned the challenged Exjade activities. However, Novartis has since learned from the author of the notes that they were written in 2015—after the time period to which the parties have agreed Novartis’s waiver of the attorney-client privilege applies—and, in fact, have no connection to Exjade activities, let alone the Exjade activities that plaintiffs challenge. (See Goldfarb Decl. ¶ 6.) Accordingly, those notes should not have been included in Novartis’s production. Therefore, pursuant to the Rule 502(d) Order entered in this case, we request that the notes be destroyed or returned to Novartis.

D. Relator’s Request to Add Two Non-Lawyer Custodians Is Untimely and Unjustified.

Relator argues that Novartis must produce documents from two additional non-lawyer custodians, Bill Conkling and Ann-Marie Redmond. However, there is no justification for Relator’s belated request for these custodians.

³ In re County of Erie, also cited by Relator, is inapposite because it did not find waiver of the privilege applicable in the first place. 546 F.3d 222, 229 (2d Cir. 2008).

Relator asserts that waiver documents show that searching Mr. Conkling's or Ms. Redmond's files "may uncover additional" material that would undermine Novartis's intent defense. (Relator's Ltr. at 11.) Not only were these documents produced nearly two months ago (on March 13, 2015), but Relator misstates their meaning and importance.

First, Relator states that, in a March 17, 2008 email, Mr. Conkling instructed one of his supervisees, Frank Padron, "to avoid legal review of a related Exjade marketing issue". (Relator's Ltr. at 11.) Relator is wrong. On its face, the legal advice addressed in the email is not "related" to the allegations in this case, but whether

REDACTED

(Relator's Ex. 9.) Such activities have never been challenged by any party in this case. Furthermore, Mr. Conkling was not, as Relator suggests, advising Mr. Padron "to avoid legal review" of that issue; instead, he was reminding Mr. Padron—who was not on the Exjade "brand" team—that "REDACTED" and that seeking advice concerning that project would "REDACTED". (Id.) If Relator really had questions about the meaning of Mr. Conkling's instructions, Relator's counsel could have asked Mr. Padron about this email at some point during Mr. Padron's nine-hour deposition (which was taken on April 11 and 27, 2015); Relator's counsel chose not to do so.

Second, Relator says another email shows that Mr. Conkling and Ms. Redmond participated in a meeting on May 7, 2008, concerning Novartis's decision to continue seeking legal advice with respect to the reallocation of undesignated Exjade prescriptions among the three EPASS pharmacies. (Relator's Ltr. at 11.) Relator fails to mention that any such meeting would have included Paul Pochtar, Kenneth Olsen, Frank Padron and Michael Mignogna, whose documents have been produced and who will be, or have already been, deposed. (Relator's Ex. 10.) Relator will have ample opportunity to seek information concerning this meeting from those other attendees. In fact, Relator's counsel marked this document as an exhibit at Mr. Padron's deposition but chose not to ask Mr. Padron any questions about the meeting it describes.

Third, the other emails involving Ms. Redmond do not demonstrate that she has evidence justifying the review and production of her files at this late date. Although Relator cites emails to show Ms. Redmond may have had some involvement in seeking advice from Mr. Metro and Keary Dunn (Relator's Exs. 11, 12), Novartis already has produced, or has agreed to produce, documents from the files of those lawyers. Furthermore, Relator offers no support for his insinuations that Ms. Redmond somehow has information showing that unnamed others at Novartis were ignoring legal advice from in-house counsel. (Relator's Ltr. at 11-12.) Relator cites an email from September 2011, near the end of the period of activities challenged in this case, in which Ms. Redmond asks for advice concerning the possible use of an "ROI" to allocate undesignated patients. (Relator's Ex. 12.) But Novartis never adopted the ROI proposal Ms. Redmond suggested. Any advice Novartis counsel may have given Ms. Redmond about such a proposal does not demonstrate that persons at Novartis failed to follow legal advice.

II. Relator's Request that Novartis Answer Relator's Interrogatories Number 5 and 6 Should Be Denied Because Novartis Has Responded to Them Adequately.

Relator contends that Novartis's responses to Interrogatories Nos. 5 and 6, which seek information regarding its revenues and profit margins on sales of Exjade through the EPASS hub, are inadequate. However, as Novartis has explained to Relator during meet and confers, it simply does not maintain information in the manner demanded by these discovery requests. Novartis has provided the nearest equivalent information that it does maintain, as well as an explanation of that information to ensure Relator is able to create the analysis he seeks. Accordingly, Novartis has met its burden under the Federal Rules.

In responding to interrogatories, a corporation need only provide "the information available to [it]". Fed. R. Civ. P. 33(b)(1)(B). Here, the interrogatories at issue seek revenue and margin information on Novartis sales of Exjade through EPASS, but Novartis does not track revenue and margin information on Exjade sales through EPASS (or through any specific specialty pharmacy or group of pharmacies, for that matter). Thus, the information requested is not available to Novartis, and Novartis has no obligation to manufacture it for Relator. See Lobosco v. I.R.S., No. 77 C. 1464, 1977 WL 1321, at *5 (E.D.N.Y. Nov. 29, 1977) ("Defendant is correct in stating that the purpose of civil discovery is not to compel the opposite party to manufacture information he does not presently possess."); 8B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2174 (3d ed. 2015) ("As a general rule a party in answering interrogatories must furnish information that is available to it and that can be given without undue labor and expense. . . . [I]nterrogatories that require a party to make extensive investigations, research, or compilation or evaluation of data for the opposing party are in many circumstances improper. A party should provide relevant facts reasonably available to it but should not be required to enter upon independent research in order to acquire information merely to answer interrogatories.").⁴

Rather than simply object on this ground—as Novartis was entitled to do—Novartis directed Relator to the nearest equivalent information that it does maintain (and which it produced to the Government during the investigation): sales and discount/rebate information for specialty pharmacies with which Novartis had discount/rebate contracts for Exjade. Although Relator objects to Novartis's production of "a large and complicated spreadsheet" (see Relator's Ltr. at 12), Novartis identified letters from its counsel to the Government explaining the spreadsheet, which ensures Relator is able to interpret the data and create whatever analysis it believes it needs to pursue its case. Notably, the Government never voiced any concern with its ability to interpret this spreadsheet, and indeed Relator appears to acknowledge that it has the facility to do so. (See Relator's Ltr. at 12 ("Arriving at the answer requires subtracting, from the 'gross sale amount' field, the amounts shown in the 'rebate' and 'chargeback' fields."); id. at 13 (claiming the interrogatories are "straightforward" and require only "relatively simple

⁴ Relator's reliance on Tyson is misplaced. There, the responding party acknowledged that it could locate the requested information by examining its documents, and the only dispute was whether it could refuse to provide a narrative response by instead producing documents under Fed. R. Civ. P. 33(d). See Tyson v. King, No. 98 Civ.1628 (LMM)(DFE), 1998 WL 823667, at *1 (S.D.N.Y. Nov. 25, 1998). By contrast, Novartis does not maintain information in the manner demanded by the interrogatories.

calculations”.) Again, Novartis should not be compelled to evaluate and interpret sales information for Relator, where Relator clearly can do so himself.⁵ See Espinal v. Coughlin, No. 98 CIV. 2579(RPP), 2000 WL 245879, at *1 (S.D.N.Y. Mar. 3, 2000) (“Defendants should not have to conduct a review of records in the possession of plaintiff or to which he has access and make determinations that plaintiff can do for himself.”) (citation omitted); 8B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2174 (3d ed. 2015) (“[A] party cannot ordinarily be forced to prepare its opponent’s case.”).⁶

Respectfully submitted,



Evan R. Chesler

The Honorable James C. Francis
United States Magistrate Judge
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007-1312

VIA ECF AND BY HAND

Copies w/encls. to:

All Counsel of Record

VIA ECF AND EMAIL

⁵ Prior to filing his motion to compel, Relator never identified any specific “obstacles” to his ability to interpret this spreadsheet. Instead, Relator claimed that the spreadsheet required unspecified “analysis and interpretation—probably by an expert”. (Novartis Ex. E at 3.) Although Novartis disagrees with this assertion, Relator is of course able to consult with an expert should he choose to do so.

⁶ Relator points to a financial statement regarding corporate-wide margin data for Novartis AG—Novartis’s parent company in Basel, Switzerland—to show that Novartis “has the means to calculate its margins” of Exjade sales through EPASS. (See Relator’s Ltr. at 13.) But the maintenance of corporate-wide margin data does not establish that Novartis possesses revenue and margin information specifically for Exjade sales through EPASS. Indeed, the financial statement cited by Relator never uses the words “Exjade” or “EPASS”.